



HOUSE OF REPRESENTATIVES

HB 2310

biological products; prescription orders
Prime Sponsor: Representative Cobb, LD 5

DP	Committee on Health
DP	Caucus and COW
X	As Transmitted to the Governor

OVERVIEW

HB 2310 permits a pharmacist to substitute a biological product for a prescribed biological product when certain conditions are met.

PROVISIONS

1. Allows a pharmacist to substitute a biological product for a prescribed biological product only if all the following conditions are met:
 - a. The United States Food and Drug Administration (FDA) have determined the substituted product to be an interchangeable biological product.
 - b. The prescribing physician does not designate in writing or electronically that substitution is prohibited.
 - c. The pharmacy informs the patient or person presenting the prescription of the substitution.
 - d. Within five business days after dispensing a biological product, the dispensing pharmacist or their designee makes an entry of the specific product provided to the patient, including the name of the product and the manufacturer. The communication must be conveyed by making an entry that is electronically accessible to the prescriber through an interoperable electronic medical records system, an electronic prescribing technology, a pharmacy benefit management system or a pharmacy record. Entry into an electronic records system as described is presumed to provide notice to the prescriber otherwise, the pharmacist must communicate the biological product dispensed to the prescriber using fax, telephone, electronic transmission or other prevailing means. Communication is not required if:
 - i. There is no interchangeable biological product approved by the FDA for the prescribed product.
 - ii. A refill prescription is not changed from the product dispensed on the prior filling of the prescription.
 - e. The pharmacy retains a record of the biological product dispensed.
2. Requires pharmacy staff to notify the person presenting the prescription of the price difference between the brand name drug or biological product prescribed and the generic drug or interchangeable biological product when the medical practitioner does not indicate intent to prevent substitution with a generic equivalent drug or interchangeable biological product.
3. Includes labeling requirements when a biological product or an interchangeable biological product is used.

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4. Prohibits an employer or agent of an employer of a pharmacist from requiring the pharmacist to dispense an interchangeable biological product or to substitute an interchangeable biological product for a biological product against the professional judgment of the pharmacist or the order of the prescriber.
5. Restricts a pharmacist's ability to make a substitution unless the manufacturer or distributor of the interchangeable biological product has shown that:
 - a. All products dispensed have an expiration date on the original package.
 - b. The manufacturer or distributor maintains recall and return capabilities for unsafe or defective biological products.
6. Requires the Arizona State Board of Pharmacy to maintain on its website a link to the current list of each biological product determined by the FDA to be an interchangeable product.
7. Includes interchangeable biological products in the worker's compensation statute (A.R.S. § 23-908).
8. Defines *biological product* and *interchangeable biological product*.
9. Contains a delayed effective date from and after December 31, 2016.

CURRENT LAW

A.R.S. § 32-1963.01 provides that if a medical practitioner prescribes a brand name drug and does not indicate an intent to prevent substitution, a pharmacist is permitted to fill the prescription with a generic drug. Pharmacy staff must notify the person presenting the prescription of the cost differential between a name brand and generic drug and in addition statute outlines labeling instructions.

A prescription must be dispensed as written only if the prescriber writes or clearly displays "DAW", "dispense as written", "do not substitute", "medically necessary" or any statement by the prescriber that clearly indicates an intent to prevent substitution. An out-of-state prescription must be dispensed as written only if the prescriber clearly writes or clearly displays "do not substitute", "dispense as written", "medically necessary" or any statement by the prescriber that clearly indicates intent to prevent substitution.